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EXAMINER	
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4166	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,232	TOSAYA ET AL.	
	Examiner	Art Unit	
	MARIA E. DOUKAS	4166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means for exciting the acoustic emitter; the means for acoustically coupling the acoustic energy into the deposits; the means for operating said emitter , the inflatable balloon used to administer a drug, as well as the imaging device that is integrated or co-mounted with the acoustic emitter must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "7" and "8" have both been used to designate the acoustic emitter. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no antecedent basis for the 'means for exciting said acoustic emitter'; the 'means for acoustically coupling said acoustic energy into said deposits'; or the 'means for operating said emitter' that is claimed in Claim 1. These features are presumed to invoke 35 U.S.C. 112, sixth Paragraph, however corresponding structure is not adequately defined in the specification so as to provide proper antecedent basis.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Reference to Claim 1

The "means for exciting said acoustic emitter"; the "means for acoustically coupling said acoustic energy into said deposits"; and the "means for operating said emitter" are presumed to invoke 35 U.S.C 112, sixth paragraph, however corresponding structure is not adequately described within the specification. One having ordinary skill in the art would not be able to ascertain the structure that the applicant is claiming.

The word "optionally" in claim 1 is a relative term and renders the claim indefinite. The word "optionally" does not enable one having ordinary skill in the art to ascertain whether the claimed apparatus does incorporate an administered drug.

In Reference to Claims 2-22

Claims 2-22 are dependent on claim 1, which is indefinite as indicated above. Therefore, claims 2-22 include all the limitations recited in claim 1 and are indefinite for the reasons stated above in reference to claim 1.

In Reference to Claim 23

Claim 23 is indefinite for being dependent on claim 1, which is indefinite for the reasons stated above.

Regarding claim 23, the phrase "in any manner" renders the claim indefinite because it does not limit the applicant's claimed invention. Also, the mention of "a drug" renders the claim indefinite as it is unclear whether the drug being referred to is that of claim 1 or another drug that is administered separately from the claimed apparatus.

In Reference to Claims 24-56

Claims 24-56 are indefinite for being dependent on claim 1, which is indefinite for the reasons stated above.

In Reference to Claim 57

Claim 57 is indefinite for being dependent on claim 1, which is indefinite for the reasons stated above.

Regarding claim 57, the phrase "in any manner" renders the claim indefinite because it does not limit the applicant's claimed invention.

In Reference to Claims 58-69

Claims 58-76 are indefinite for being dependent on claim 1, which is indefinite for the reasons stated above.

In Reference to Claim 70

Claim 70 is indefinite for being dependent on claim 1, which is indefinite for the reasons stated above.

Regarding claim 70, the range milliwatts/cm^2 to kilowatts/cm^2 renders the claim indefinite because it does provide a number range to limit the applicant's claimed invention.

In Reference to Claims 71-76

Claims 71-76 are indefinite for being dependent on claim 1, which is indefinite for the reasons stated above.

In Reference to Claim 77

Claim 77 is indefinite for being dependent on claim 1, which is indefinite for the reasons stated above.

Regarding claim 77, the word "optionally" in claim 1 is a relative term and renders the claim indefinite. The word "optionally" does not enable one having ordinary skill in the art to ascertain whether the claimed apparatus does incorporate an administered drug.

In Reference to Claims 78-84

Claims 78-84 are indefinite for being dependent on claim 1, which is indefinite for the reasons stated above.

In Reference to Claim 85

Claim 85 is indefinite for being dependent on claim 1, which is indefinite for the reasons stated above.

Regarding claim 85, the word "optionally" in claim 1 is a relative term and renders the claim indefinite. The word "optionally" does not enable one having ordinary skill in the art to ascertain whether the claimed apparatus does incorporate an administered drug.

In Reference to Claim 86

Claim 86 is indefinite for being dependent on claim 1, which is indefinite for the reasons stated above.

The phrase "in any manner" renders the claim indefinite because it does not limit the applicant's claimed invention.

In Reference to Claims 87-88

Claims 87-88 are indefinite for being dependent on claim 85, which is indefinite for the reasons stated above.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-84 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The "means for acoustically coupling said

acoustic energy into said deposits" is indefinite under 35 U.S.C. 112, second paragraph, as described above. Applicant does mention coupling of the acoustic energy into the implant, member, or organ on page 16, paragraph [0057] of the Specification, however applicant's description implies claiming a human being (i.e. skin, body passage, lumen, organ, cardiac structure), which is non-statutory subject matter (See MPEP §2105).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-28, 33-49, 51, 53, 55-59, 62-67, 69, 74, 79-85 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,725,494 to Brisken (Brisken'494).

In Reference to Claim 1

Apparatus (Figure 1) capable of the non-contact or damage-free removal, break-down or erosion of undesirable deposits situated: (a) on or in an implanted artificial or bioprosthetic device having at least one moving or movable part or portion,

or (b) on or in a natural bodily member or organ having a naturally moving part or portion, the deposits interfering or potentially interfering with at least one of (a) any designed function or maintenance of said implanted device, (b) any natural function of said natural bodily member or organ or (c) any circulatory system process necessary for normal healthy living, said apparatus comprising:

an acoustic emitter (resonantly vibrating assembly 40) capable of emitting acoustic energy;

a means for exciting said acoustic emitter to emit acoustic energy (power supply 14; col. 8, lines 24-37);

a means for acoustically coupling said acoustic energy into said deposits directly or indirectly (Figure 8; col. 9, lines 23-26, whereby the interface member 44 of the vibrating assembly 40 is coupled into the lumen of the blood vessel);

a means for operating said emitter(s) to at least partially remove, break-down or otherwise erode said deposits (longitudinally oscillating driver 50; col. 7, lines 32-34); and

optionally, an administered drug to aid said removal or erosion process, to prevent or slow further such deposits, or to treat a side-effect of treatment with said acoustic emitter (col. 5, lines 4-7).

In Reference to Claims 2-11

Claims 2-11 are directed towards further specifying the moving part of an implanted device or towards further specifying the deposits. These are described within

the preamble of Claim 1 in order to provide intended use, and, based on MPEP §2111.02, section II, which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, claims 2-11 are rejected, as they do not add significance to claim 1, and claim 1 has been rejected as described above.

In Reference to Claim 12

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said emitter is acoustically coupled into said deposits directly using at least one of a noninvasive, minimally invasive or invasive approach (Figure 8; col. 9, lines 23-26).

In Reference to Claim 13

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said non-contact deposition removal and lack of scratching or other damage to any portion of said implant, member or organ is provided by at least one of: (a) no portion of the emitter means contacts the implant, member or organ, (b) any portion of the emitter means that does contact the implant, member or organ is chosen to be a compliant or deformable material (Figure 8, as the interface member 44 of the vibrating assembly 40 is within the blood vessel's lumen and not in direct contact with the vessel).

In Reference to Claims 14-17

Claims 14-17 are directed towards the environment in which the claimed apparatus is used, and therefore fail to structurally distinguish the claimed apparatus from Brisken'494 (See MPEP §2111.04, §2112.01).

In Reference to Claims 18-19

Claims 14-19 are directed towards further specifying the implanted device or towards further specifying the deposits. These are described within the preamble of Claim 1 in order to provide intended use, and, based on MPEP §2111.02, section II, which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, claims 14-19 are rejected, as they do not add significance to claim 1, and claim 1 has been rejected as described above.

In Reference to Claim 20

The apparatus of Claim 19 (see rejection of claim 19 above) wherein said acoustic emissions result in at least one of (a) directly destroying said deposits, (b) thermally destroying said deposits, (c) plugging a blood-leak caused by such deposits, (d)

plugging a blood-leak and simultaneously killing at least some of said deposits, and (e) serving as a therapy for endocarditis (col. 9, lines 28-31).

In Reference to Claim 21

The apparatus of Claim 20 (see rejection of claim 20 above) wherein acoustic emissions are directed at at least some said deposits surrounding a natural or prosthetic valve (col. 9, lines 21-31, whereby the apparatus is capable of directing the ultrasonic vibrations towards a valve by advancing the catheter with the interface member 44 through the blood vessel towards a valve) and said deposits are at least partly killed by at least one of direct acoustic radiation or heat generated by acoustic radiation (Brisken'494 is capable of performing the stated intended use, because as taught in col. 9, lines 21-31, as the acoustic emissions are delivered directly to the thrombus via a catheter, which is how applicant described killing deposits on page 24, paragraph [0079] of the specification; col. 6, lines 49-51, and the frequency is within the range applicant lists as preferable on page 16, paragraph [0058] of the specification).

In Reference to Claim 22

The apparatus of Claim 20 (see rejection of claim 20 above) wherein acoustic emissions are directed, at least in part, to a prosthetic valve component whereby acoustic heating of said component causes heat to be conducted into adjacent endocarditis-laden tissue, said endocarditis bacteria or fungus being at least in part killed by said conducted thermal energy (see rejection of claim 21 above, whereby the apparatus is capable of

directing emissions towards a prosthetic valve as the catheter can be advanced through the blood vessel lumen to reach the valve, and this treatment is capable of being conducted on endocarditis-laden tissue, which would then cause the bacteria to be at least partly killed as described in rejection of claim 21 above).

In Reference to Claims 23-24

Claims 23-24 are directed towards the environment in which the claimed apparatus is used, and therefore fail to structurally distinguish the claimed apparatus from Brisken'494 (See MPEP §2111.04, §2112.01).

In Reference to Claim 25

The apparatus of Claim 20 (see rejection of claim 20 above) wherein said acoustic emissions are delivered to the valve or implant from a catheter or other lumen-delivered device (col. 9, lines 21-31, whereby the apparatus is capable of being used to deliver emissions towards a valve or implant by advancing the catheter towards one of these structures).

In Reference to Claim 26

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said drug is employed at least one of before, during or after an acoustic exposure in order to aid in removal, breakdown or erosion of said deposits or to ameliorate a side-effect of the acoustic therapy (col. 9, lines 32-35).

In Reference to Claim 27

The apparatus of Claim 26 (see rejection of claim 26 above) wherein said acoustic energy accelerates or enables any favorable action of said drug (col. 5, lines 12-14).

In Reference to Claim 28

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said acoustic energy has a frequency with a wavelength on the order of a characteristic dimension of said deposits or of a deposit constituent in order to enhance acoustic coupling to the deposit or deposit constituent (col. 6, lines 49-51, whereby the frequency that the vibrating assembly 40 operates at is within the 5kHz - 10 MHz range that applicant mentions in the specification page 16, paragraph [0058] as being the preferable frequency range for the apparatus. This frequency range is therefore assumed to be what is claimed).

In Reference to Claim 33

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said acoustic energy aids in the permeation of said deposits by at least one of a drug or a blood constituent col. 5, lines 12-14).

In Reference to Claim 34

Claim 34 is directed towards further specifying the deposits. These are described within the preamble of Claim 1 in order to provide intended use, and, based on MPEP

§2111.02, section II, which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, claim 34 is rejected, as it does not add significance to claim 1, and claim 1 has been rejected as described above.

In Reference to Claim 35

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said drug is selected from the group consisting of (1) thrombolytic therapy or clot-dissolving drugs, (2) tissue plasminogen activators or a type thereof, (3) anti-clotting, anti-coagulant or anti-platelet drugs, and (4) thrombin inhibitor or anti-platelet drugs (col. 5, lines 14-17).

In Reference to Claim 36

The apparatus of Claim 35 (see rejection of claim 35 above) wherein said drug is selected from the group consisting of alteplase, anistreplase, streptokinase, urokinase, warfarin, 25 heparin, lepirudin, aspirin, ticlopidine, clopidogrel, tirofiban, and eptifibatide (col. 5, lines 14-17).

In Reference to Claim 37

The apparatus of Claim 35 (see rejection of claim 35 above) wherein said drug is utilized at least one of before, during or after said treatment (col. 9, lines 32-35).

In Reference to Claim 38

Claim 38 is directed towards the environment in which the claimed apparatus is used, and therefore fail to structurally distinguish the claimed apparatus from Brisken'494 (See MPEP §2111.04, §2112.01).

In Reference to Claims 39-41

Claims 39-41 are directed towards further specifying the implant. This is described within the preamble of Claim 1 in order to provide intended use, and, based on MPEP §2111.02, section II, which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, claims 39-41 are rejected, as they do not add significance to claim 1, and claim 1 has been rejected as described above.

In Reference to Claims 42-44

Claims 43-44 are directed towards the environment in which the claimed apparatus is used, and therefore fail to structurally distinguish the claimed apparatus from Brisken'494 (See MPEP §2111.04, §2112.01).

In Reference to Claim 45

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said direct energy deposition upon or into said deposits involves said emissions passing through at least one blood, liquid or tissue path between said emitter and said deposits (col. 9, lines 23-31, as since the apparatus is placed within the blood vessel lumen the emissions will pass through a blood path).

In Reference to Claims 46-47

Claims 46-47 are directed towards the environment in which the claimed apparatus is used, and therefore fail to structurally distinguish the claimed apparatus from Brisken'494 (See MPEP §2111.04, §2112.01).

In Reference to Claims 48-49

Claims 48-49 are directed towards further specifying the deposits. These are described within the preamble of Claim 1 in order to provide intended use, and, based on MPEP §2111.02, section II, which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, claims 48-49 are rejected, as they do not add significance to claim 1, and claim 1 has been rejected as described above.

In Reference to Claim 51

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said acoustic emitter is at least temporarily integrated either into the patient's body or into said implant itself (col. 9, lines 23-26).

In Reference to Claim 53

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said acoustic emitter is one of a piezoelectric, ferroelectric, electrostrictive, magnetostrictive, optoacoustic or thermoacoustic emitter (col. 7, lines 34-36, lines 44-45).

In Reference to Claims 55-56

Claim 55 is directed towards the environment in which the claimed apparatus is used, and therefore fail to structurally distinguish the claimed apparatus from Brisken'494 (See MPEP §2111.04, §2112.01).

In Reference to Claim 57

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said drug is locally delivered to said deposits in any manner (col. 9, lines 31-35).

In Reference to Claim 58

The apparatus of Claim 57 (see rejection of claim 57 above) wherein said local delivery is via a catheter or working port of a scope (col. 9, lines 31-35).

In Reference to Claim 59

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said acoustic energy is coupled into said implant, member or organ by (a) coupling to a patient's external skin, (b) coupling from within a patient's natural body passage or space, (c) coupling into the surface of a surgically exposed or accessed organ or tissue surface, (d) coupling from a lumen as by a catheter, or (e) coupling from within a cardiac chamber or flowpath (col. 9, lines 21-26).

In Reference to Claims 62-63

Claims 62-63 are directed towards the environment in which the claimed apparatus is used, and therefore fail to structurally distinguish the claimed apparatus from Brisken'494 (See MPEP §2111.04, §2112.01).

In Reference to Claim 64

Claim 64 is directed towards further specifying the deposits. These are described within the preamble of Claim 1 in order to provide intended use, and, based on MPEP §2111.02, section II, which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, claim 64 is

rejected, as it does not add significance to claim 1, and claim 1 has been rejected as described above.

In Reference to Claim 65

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said acoustic energy is within a range of 1 Hz to 100 MHz (col. 6, lines 49-51).

In Reference to Claim 66

The apparatus of Claim 65 (see rejection of claim 65 above) wherein said acoustic energy is within a range of 1 KHz to 10 MHz (col. 6, lines 49-51).

In Reference to Claim 67

The apparatus of Claim 66 (see rejection of claim 66 above) wherein said acoustic energy is within a range of 5 KHz to 10 MHz (col. 6, lines 49-51).

In Reference to Claim 69

The apparatus of Claim 65 (see rejection of claim 65 above) wherein any parameter of said acoustic energy is chosen for its ability to remove said deposits upon direct radiation by said acoustic energy (col. 9, lines 28-31, whereby the vibrating assembly 40 causes mechanical disruption of the thrombus, and the parameter that is chosen is the frequency range that is listed in col. 6, lines 49-51).

In Reference to Claim 74

Claim 74 is directed towards further specifying the deposits. These are described within the preamble of Claim 1 in order to provide intended use, and, based on MPEP §2111.02, section II, which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, claim 74 is rejected, as it does not add significance to claim 1, and claim 1 has been rejected as described above.

In Reference to Claims 79-82

Claims 79-82 are directed towards further specifying the deposits and the member the deposits are found on. These are described within the preamble of Claim 1 in order to provide intended use, and, based on MPEP §2111.02, section II, which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, claims 79-82 are rejected, as they do not add significance to claim 1, and claim 1 has been rejected as described above.

In Reference to Claim 83

The apparatus of claim 1 (see rejection of claim 1 above) wherein the emitter therapy allows for a reduction in the use of any anti-deposit drug or avoidance of use of any anti-deposit drug which would have been otherwise used, at any point, if not for the availability of the emitter therapy (col. 4, lines 27-29).

In Reference to Claim 84

Claim 84 is directed towards further specifying the member. This is described within the preamble of Claim 1 in order to provide intended use, and, based on MPEP §2111.02, section II, which states, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." Therefore, claim 84 is rejected, as it does not add significance to claim 1, and claim 1 has been rejected as described above.

In Reference to Claim 85

An acoustic method capable of the non-contact removal, break-down or erosion of undesirable deposits on or in an implant comprising an implanted artificial or bioprosthetic device having at least one moving or movable part or portion, the deposits interfering or potentially interfering with at least one of (a) the designed proper functioning or maintenance of said implant or (b) a natural

circulatory system process necessary for normal living, said method comprising:

providing an acoustic emitter (vibrating assembly 40) capable of emitting acoustic energy (col. 9, lines 23-26);

exciting said acoustic emitter to emit said acoustic energy (col. 9, lines 26-28);

acoustically coupling said acoustic energy into said deposits, directly or indirectly, to at least partially remove, break-down or otherwise erode said deposits (col. 9, lines 28-30);

either passing said at least partially removed deposits or otherwise broken-down or eroded deposits into the body or physically removing said at least partially removed deposits or otherwise eroded or broken-down deposits by a collection or trapping means (col. 9, lines 28-31); and

optionally administering a drug to aid said removal, said deposits thereby being at least partially removed from said implant (col. 9, lines 32-35).

10. Claims 1 and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. US 2003/0009153 to Brisken (Brisken'153).

In Reference to Claim 1

Apparatus (Figure 3A, integrated device 40) capable of the non-contact or damage-free removal, breakdown or erosion of undesirable deposits situated: (a) on or in an implanted artificial or bioprosthetic device having at least one moving or movable part or portion, or (b) on or in a natural bodily member or organ having a naturally moving part

or portion, the deposits interfering or potentially interfering with at least one of (a) any designed function or maintenance of said implanted device, (b) any natural function of said natural bodily member or organ or (c) any circulatory system process necessary for normal healthy living, said apparatus comprising:

an acoustic emitter (vibrational emitter 30) capable of emitting acoustic energy;

a means for exciting said acoustic emitter to emit acoustic energy (page 7, paragraph [0085]);

a means for acoustically coupling said acoustic energy into said deposits directly or indirectly (Figure 5A, page 7, paragraphs [0086], [0092]);

a means for operating said emitter(s) to at least partially remove, break-down or otherwise erode said deposits (Figure 3A; page 7, paragraph [0086]); and

optionally, an administered drug to aid said removal or erosion process, to prevent or slow further such deposits, or to treat a side-effect of treatment with said acoustic emitter (page 7, paragraph [0086]).

In Reference to Claim 73

The apparatus of Claim 1 (see rejection of claim 1 above) wherein said acoustic energy is delivered by at least one of a focused, unfocused or collimated beam transducer and said acoustic emitter is at least one of mechanically focused or electronically focused (page 8, paragraph [0095]).

11. Claims 1 and 75 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0024347 to Wilson (Wilson).

In Reference to Claim 1

Apparatus (Figure 1; ultrasonic catheter 10) capable of the non-contact or damage-free removal, breakdown or erosion of undesirable deposits situated: (a) on or in an implanted artificial or bioprosthetic device having at least one moving or movable part or portion, or (b) on or in a natural bodily member or organ having a naturally moving part or portion, the deposits interfering or potentially interfering with at least one of (a) any designed function or maintenance of said implanted device, (b) any natural function of said natural bodily member or organ or (c) any circulatory system process necessary for normal healthy living, said apparatus comprising:

an acoustic emitter (ultrasound assembly 42) capable of emitting acoustic energy;

a means for exciting said acoustic emitter to emit acoustic energy (page 5, paragraph [0065], [0068], [0069]);

a means for acoustically coupling said acoustic energy into said deposits directly or indirectly (page 9, paragraph [0106]);

a means for operating said emitter(s) to at least partially remove, break-down or otherwise erode said deposits (page 9, paragraphs [0106-0107]); and

optionally, an administered drug to aid said removal or erosion process, to prevent or slow further such deposits, or to treat a side-effect of treatment with said acoustic emitter (page 9, paragraph [0112]).

In Reference to Claim 75

The apparatus of Claim 74 wherein said acoustic energy has a frequency within a range of 3 to10 MHz and an acoustic power of several hundred to a few thousand watts/cm^2 at the most intense portion of the beam (page 5, paragraph [0067]).

12. Claims 86-87 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication No. 2001/0039383 to Mohler (Mohler).

In Reference to Claim 86

A method of assessing the state of fouling by undesirable deposits of an implant or of a natural valve in a living body, the implant or valve having at least one moving or movable part, said method comprising:

obtaining, in any manner, an acoustic signature of the operation of said implant or valve or valve-model at least under unfouled conditions inside or outside a living body (page 3, paragraph [0056]);

obtaining, in any manner, using passive reception or pulse-echo active probing, an acoustic signature of said implant or valve thought to possibly have fouling thereon or therein (page 8, paragraphs [0127], whereby the increased frequency detected can

be indicative of fouling as the apparatus can be used for detecting thrombosis (page 2, paragraph [0019]);

the possibly-fouled signature containing at least one of: (1) naturally generated acoustic features known to be caused by fouling, and (2) artificially excited features known to be excited upon the presence of fouling (page 2, paragraph [0019]; page 9, paragraph [0132], whereby it is stated this apparatus can be used to detect occlusions and thrombosis, and since the acoustic features (frequency components) could be altered by increasing the subject's blood pressure they would be altered by the presence of fouling since fouling will result in an increased blood pressure due to restricted blood flow);

comparing the fingerprints looking for fouling features that have newly been incorporated into the signature (page 9, paragraphs [0133], whereby the use of pressure/frequency curves to estimate blood pressure can also be used to provide a means for comparison to detect fouling, as fouling will also increase blood pressure); and

concluding that newly added features which match known fouling features indicate fouling (page 2, paragraph [0019], as it states that the sounds can be used to detect thrombosis and occlusions among other things).

In Reference to Claim 87

The method of Claim 86 (see rejection of claim 86 above) wherein said acoustic signature fouling feature relates to acoustics generated by a fouling deposit or

modifications to the normal unfouled acoustics expected of an unfouled moving or movable implant part or of blood moving therein or thereby (page 2, paragraph [0019]; page 9, paragraphs [0132-0133], whereby it states that the apparatus can be used to detect thrombosis and occlusions, and it is possible to detect a frequency change to correlate with blood pressure increase. This apparatus can then be used to detect the same frequency changes to show different acoustics presented due to fouling).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 29-30, 52, 68, and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brisken'494 in view of U.S. Patent No. 6,361,554 to Brisken (Brisken'554).

In Reference to Claim 29

Brisken'494 teaches the apparatus of claim 1 (see rejection of claim 1 above), but fails to teach wherein said acoustic energy has a frequency with a wavelength which purposely excites a resonance or resonance harmonic in a portion of the implanted device or purposely avoids such a resonance.

Brisken'554 teaches wherein said acoustic energy has a frequency with a wavelength which purposely excites a resonance or resonance harmonic in a portion of the implanted device or purposely avoids such a resonance (col. 2, lines 54-57; col. 4, lines 19-23) in order to allow the implant to resonate and reradiate the vibrational energy into the surrounding blood vessel wall (col. 3, lines 59-64).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have selected an acoustic emitter and means for exciting capable of operating at the frequency of Brisken'554 to use in the apparatus of Brisken'494 in order to allow an implanted structure to resonate when excited by externally applied acoustic energy and reradiate the vibrational energy into the surrounding blood vessel wall as explicitly taught by Brisken'554.

In Reference to Claim 30

Brisken'494 in view of Brisken'554 teaches the apparatus of claim 29 (see rejection of claim 29 above) and Brisken'554 teaches wherein said resonant excitation contributes to indirect delivery of acoustic energy into said deposits and said indirectly-delivered energy contributes to removal, break-down or erosion of said deposits in order to allow the implant to resonate and reradiate the vibrational energy into the surrounding blood vessel wall to provide indirect delivery of acoustic energy (col. 3, lines 59-64).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have included the stent or vascular graft structure of Brisken'554 into the blood vessel treated with the apparatus of Brisken'494 in order to provide a means

for indirectly delivering acoustic emissions into deposits in the vessel wall as explicitly taught by Brisken'554.

In Reference to Claim 52

Brisken'494 teaches the apparatus of claim 51 (see rejection of claim 51 above), but fails to teach wherein said acoustic emitter can be automatically operated without constant patient or doctor manipulation. Brisken'554 teaches wherein said acoustic emitter can be automatically operated without constant patient or doctor manipulation (col. 3, lines 33-36, lines 43-46) in order to ease the treatment delivery.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the apparatus of Brisken'494 to include an implanted stent that is capable of resonating and reradiating the vibrational energy into the surrounding blood vessel when excited in order to enable automatic operation without patient or doctor manipulation and to ease treatment delivery as implicitly taught by Birsken'554.

In Reference to Claim 68

Brisken'494 teaches the apparatus of claim 65 (see rejection of claim 65 above), but fails to teach wherein said acoustic energy is chosen to either: (a) not excite a known resonance of said implant, or (b) to excite a known resonance of said implant below an amplitude that would damage the implant. Brisken'554 teaches wherein said acoustic energy is chosen to either: (a) not excite a known resonance of said implant, or

(b) to excite a known resonance of said implant below an amplitude that would damage the implant (col. 4, lines 20-23) in order to allow the implant to resonate and reradiate the vibrational energy into the blood vessel wall (col. 3, lines 59-64).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have included the implant of Brisken'554 into the blood vessel treated with the apparatus of Brisken'494 in order to allow the implant to resonate and reradiate the vibrational energy into the blood vessel wall to treat the deposits as explicitly taught by Brisken'554.

In Reference to Claim 70

Brisken'494 teaches the apparatus of claim 1 (see rejection of claim 1 above), but fails to teach wherein said acoustic energy has an acoustic power within a range of milliwatts/cm^2 to kilowatts/cm^2. Brisken'554 teaches wherein said acoustic energy has an acoustic power within a range of milliwatts/cm^2 to kilowatts/cm^2 (col. 3, lines 14-16) in order to provide treatment for reducing hyperplasia.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have included an acoustic emitter and means for exciting that is capable of generating acoustic power within a range of milliwatts/cm^2 to kilowatts/cm^2 within the apparatus of Brisken'494 in order to provide the desired power for treatment as implicitly taught by Brisken'554.

In Reference to Claim 71

Brisken'494 further in view of Brisken'554 teaches the apparatus of claim 70 (see rejection of claim 70 above) and Brisken'554 teaches wherein said power is within a range of 0.5 to 5,000 watts/cm^2 (col. 3, lines 14-16).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have included an acoustic emitter and means for exciting that is capable of generating this power range for use in the apparatus of Brisken'494 in order to provide the desired treatment as implicitly taught by Brisken'554.

In Reference to Claim 72

Brisken'494 further in view of Brisken'554 teaches the apparatus of claim 71 (see rejection of claim 71 above) and Brisken'554 teaches wherein said power is within a range of 5 to 500 watts/cm^2 (col. 3, lines 14-16).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have included an acoustic emitter and means for exciting that is capable of generating this power range for use in the apparatus of Brisken'494 in order to provide the desired treatment as implicitly taught by Brisken'554.

15. Claims 31-32, 50, 54, 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brisken'494 in view of U.S. Patent No. 4,870,953 to DonMicheal (DonMicheal).

In Reference to Claim 31

Brisken'494 teaches the apparatus of claim 1 (see rejection of claim 1 above), but fails to teach wherein said acoustic energy causes at least one of blood streaming, cavitation, erosion, break-down or dissolution in the region of said deposits. DonMicheal teaches wherein said acoustic energy causes at least one of blood streaming, cavitation, erosion, break-down or dissolution in the region of said deposits (col. 6, lines 1-6) in order to break up and dissolve plaque formed within a blood vessel (col. 5, lines 67-68; col. 6, lines 1-6).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the resonantly vibrating assembly 40 of Brisken'494 to have the ultrasonic movement of the probe 6 of DonMicheal in order to break up and dissolve plaque formed within a blood vessel as explicitly taught by DonMicheal.

In Reference to Claim 32

Brisken'494 further in view of DonMicheal teaches the apparatus of claim 31 (see rejection of claim 31 above) and DonMicheal teaches wherein said streaming or cavitation aids the removal, break-down or erosion of at least a portion of said deposits (col. 6, lines 1-6) in order to further break up and dissolve plaque formed within a blood vessel (col. 5, lines 67-68; col. 6, lines 1-6).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the resonantly vibrating assembly 40 of Brisken'494 to

have the ultrasonic movement of the probe 6 of DonMicheal to further break up and dissolve plaque formed within a blood vessel as explicitly taught by DonMicheal.

In Reference to Claim 50

Brisken'494 teaches the apparatus of claim 1 (see rejection of claim 1 above), but fails to teach wherein said deposits include pannus growth and said acoustic energy is used to either stop said pannus growth or remove said pannus growth by cavitation, heating or thermal necrosis. DonMicheal teaches wherein acoustic energy via cavitation is used (col. 6, lines 1-3) in order to remove plaque formed within blood vessels (col. 6, lines 1-6).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the resonantly vibrating assembly 40 of Brisken'494 to have the ultrasonic movement of the probe 6 of DonMicheal and then used this device and the cavitation to remove pannus growth as opposed to removing plaque as explicitly taught by DonMicheal.

In Reference to Claim 54

Brisken'494 teaches the apparatus of claim 1 (see rejection of claim 1 above) but fails to teach wherein said acoustic emitter is integrated or co-mounted with an imaging device selected from the group consisting of an ultrasound transducer, an infrared camera or an imaging scope of any type. DonMicheal teaches wherein said acoustic emitter is integrated or co-mounted with an imaging device selected from the group

consisting of an ultrasound transducer, an infrared camera or an imaging scope of any type (col. 6, lines 14-25) in order to enable the physician to observe the catheter location in the blood vessel and monitor the ultrasonic treatment (col. 6, lines 20-25).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have included the imaging device of DonMicheal with the apparatus of Brisken'494 in order to enable the physician to observe the catheter location in the blood vessel and monitor the ultrasonic treatment as explicitly taught by DonMicheal.

In Reference to Claim 76

Brisken'494 teaches the apparatus of claim 74 (see rejection of claim 74 above), but fails to teach wherein said acoustic energy causes said pannus to be killed via thermal heating and/or cavitation. DonMicheal teaches acoustic energy causing thermal heating and/or cavitation (col. 6, lines 1-6) in order to further break up plaque particles (col. 6, lines 5-6).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the resonantly vibrating assembly 40 of Brisken'494 to have the ultrasonic movement of the probe 6 of DonMicheal in order to provide cavitation that could be used to kill pannus instead of used to break up plaque as explicitly taught by DonMicheal.

In Reference to Claim 77

Brisken'494 teaches the apparatus of claim 1 (see rejection of claim 1 above), but fails to teach wherein said acoustic energy causes beneficial cavitation, said cavitation optionally being aided by the presence of cavitation nuclei or facilitators. DonMicheal teaches wherein said acoustic energy causes beneficial cavitation, said cavitation optionally being aided by the presence of cavitation nuclei or facilitators (col. 6, lines 2-4) in order to further break up the plaque particles within the blood vessel (col. 6, lines 4-6).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the resonantly vibrating assembly 40 of Brisken'494 to have the ultrasonic movement of the probe 6 of DonMicheal in order to provide cavitation and cavitation nuclei factors to further break up the plaque particles as explicitly taught by DonMicaheal.

In Reference to Claim 78

Briskn'494 further modified by DonMicheal teaches the apparatus of claim 77 (see rejection of claim 77 above), and DonMicheal teaches said cavitation nuclei or facilitators are selected from the group consisting of contrast microbubbles, gas bubbles, and surfactants (col. 6, lines 2-4) in order to further break up the plaque particles within the blood vessel (col. 6, lines 4-6).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the resonantly vibrating assembly 40 of Brisken'494 to

have the ultrasonic movement of the probe 6 of DonMicheal in order to provide cavitation and cavitation nuclei factors to further break up the plaque particles as explicitly taught by DonMicheal.

16. Claims 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brisken'494 in view of U.S. Patent No. 5,853,005 to Scanlon (Scanlon).

In Reference to Claim 60

Brisken'494 teaches the apparatus of claim 1 (see rejection of claim 1 above), but fails to teach wherein said acoustic emitter also comprises or is co-mounted, co-packaged or used in association with an acoustic device used to gather an acoustic fingerprint indicative of the extent, location or nature of deposits. Scanlon teaches an acoustic device (acoustic monitoring system 10) used to gather an acoustic fingerprint (col. 7, lines 6-10) in order to monitor biological activity (col. 1, lines 44-45), which can potentially be used to monitor the location and nature of deposits.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have included the acoustic monitoring system of Scanlon with the acoustic emitter of Brisken'494, and then to have used this to monitor the location and nature of deposits as implicitly taught by Scanlon.

In Reference to Claim 61

Brisken'494 teaches the apparatus of claim 1 (see rejection of claim 1 above), but fails to teach wherein one or more acoustic fingerprints are taken or generated by

an at least second acoustic device independent of said acoustic emitter, the acoustic fingerprint or fingerprints being indicative of the extent, location or nature of deposits. Scanlon teaches wherein one or more acoustic fingerprints are taken or generated by an at least second acoustic device (acoustic monitoring system 10) independent of said acoustic emitter (col. 1, lines 44-45), which can potentially be used to monitor the location and nature of deposits.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have included the acoustic monitoring system of Scanlon with the acoustic emitter of Brisken'494, and then to have used this to monitor the location and nature of deposits as implicitly taught by Scanlon.

17. Claim 88 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohler as applied to claim 86 above in view of U.S. Patent No. 5,853,005 to Scanlon (Scanlon).

Mohler teaches the method of claim 86 (see rejection of claim 86 above), but fails to teach wherein said implant or valve is imaged and said acoustic signature is synchronized with the motion of said implant or valve. Scanlon teaches wherein said implant or valve is imaged and said acoustic signature is synchronized with the motion of said implant or valve (col. 7, lines 14-24) in order to be able to both hear and see the valve closing (col. 7, lines 23-24).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have included one of the imaging modalities mentioned in Scanlon with

the acoustic detecting apparatus of Scanlon in order to be able to simultaneously hear and see the valve closing as explicitly taught by Scanlon.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 7,335,169 (Thompson) discloses an ultrasound apparatus to treat vascular diseases. U.S. Patent No. 6,635,017 (Moehring) discloses a method and apparatus to both monitor and treat thrombosis using ultrasound. U.S. Patent No. 3,433,226 (Boyd) teaches ultrasound treatment that produces debris of fine enough size to pass through the circulatory system. U.S. Patent Application Publication US 2003/0171803 (Shimon) teaches delivery of a drug from an inflatable balloon.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ken Bomberg can be reached on (571)272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD

/Kenneth Bomberg/

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